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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,429	01/22/2002	Ekambar R. Kandimalla	47508-580 (HYZ-027CIP)	7279

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BOSTON, MA 02109

EXAMINER

EPPS FORD, JANET L

ART UNIT	PAPER NUMBER
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1633

DATE MAILED: 08/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/054,429

Applicant(s)

KANDIMALLA ET AL.

Examiner

Janet L. Epps-Ford

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3,5,8-13,16,17 and 20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5,8-13,16,17 and 20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 4-26-06.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. Claims 1-3, 5, 8-13, 16-17, and 20 are pending.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Response to Amendment***

3. The rejection of claims 18-19 under 35 U.S.C. 102(e) as being anticipated by Agrawal et al. (US Patent No. 6,489,464 B1), is withdrawn in response to Applicant's cancellation of claims 18-19.

#### ***Response to Arguments***

##### ***Claim Rejections - 35 USC § 103***

4. Claims 1-3, 5, 8-13, 16-17 and 20 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Gryaznov et al. (US Patent No. 5,571,903) in view of Weber et al. (1992), for the reasons of record set forth in the prior Office Action.
5. Applicant's arguments filed 5-30-06 have been fully considered but they are not persuasive. Applicants traverse the instant rejection on the grounds that "the non-covalent binding pair contemplated by the '903 patent (as in Applicants claimed invention), is a lipophilic group, therefore according to Applicants, "it is not appropriate to substitute the strong hydrogen bonding pair taught by Weber with the relatively weak lipophilic binding pair contemplated by the '903 patent." On this basis, Applicant requested that the rejection be withdrawn.

Applicants have improperly interpreted the terminal binding moieties that form stable non-covalent complexes of the '903 patent to solely encompass lipophilic non-

covalent binding groups. Contrary to Applicant's assertions, it is clear that other binding groups besides lipophilic binding groups are contemplated by the '903 patent. The only requirement for these groups is that upon annealing of the oligonucleotide moieties to a target polynucleotide, the terminal binding moieties of each pair form a stable covalent or non-covalent complex (col. 3, lines 25-30).

As stated in the prior Office Action, absent evidence to the contrary, the binding pairs of Weber et al. meet all the characteristics of the terminal binding moieties contemplated by Gryaznov et al. Specifically, Gryaznov et al. teach that the terminal binding pairs must form stable and specific complexes (col. 6, lines 51-54), and Weber et al. teach that streptavidin and biotin are known to form highly specific complexes with high affinity. Moreover, Gryaznov et al. teach that a variety of binding pairs can be used in combination with their invention, as long as the binding pairs meet the required characteristics. Absent evidence to the contrary, due to the known high affinity shared between streptavidin and biotin, and their ability to form highly specific complexes, it would have been obvious at the time of the instant invention to substitute one functionally equivalent binding pair for another with the expectation that the binding pair of Weber et al. would function in the same manner as those described in Gryaznov et al.

Applicants have not provided any objective evidence to support their assertions of no expectation of success, i.e. lack of enablement of the prior art teachings. If a prima facie case of obviousness is established, the burden shifts to the applicant to come forward with arguments and/or evidence to rebut the prima facie case. It is

emphasized that the arguments of counsel alone cannot take the place of factually supported objective evidence to obviate a prima facie case of obviousness. See MPEP § 2144.

***Conclusion***

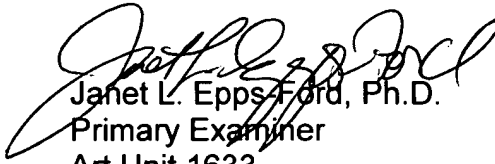
6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave T. Nguyen can be reached on 571-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Janet L. Epps-Ford, Ph.D.  
Primary Examiner  
Art Unit 1633

JLE